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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK FEMCARE AG, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk FemCare AG (collectively, "Plaintiffs" or "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Defendant" or "Teva") allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Teva's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), by which Teva seeks approval to market a generic version of Novo Nordisk's pharmaceutical product, Vagifem®, prior to the expiration of United States Patent No. 7,018,992 ("the '992 patent") and United States Patent No. 5,860,946 ("the '946 patent"), which cover, inter alia, a method and an instrument for administering Vagifem®.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of Delaware, and maintains its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

3. Plaintiff Novo Nordisk FemCare AG ("NNFCAG") is an entity organized and existing under the laws of Switzerland, having a place of business at Thurgauerstrasse 36-38, Zurich, Switzerland.

4. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044. On information and belief, Teva is a wholly owned subsidiary and agent of Teva Pharmaceutical Industries, Ltd. Teva has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by filing lawsuits and

asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Teva by virtue of, inter alia, Teva's presence in New Jersey, having conducted business in New Jersey and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of New Jersey.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

8. On March 28, 2006, the United States Patent and Trademark Office issued the '992 patent,[1] entitled "Hormone Composition," a copy of which is attached to this Complaint as Exhibit A. At the time of its issue, the '992 patent was assigned to Novo Nordisk A/S. NNFCAG currently is the owner of all right, title, and interest in and to the '992 patent. NNI and NNFCAG are indirect, wholly owned subsidiaries of Novo Nordisk A/S.

9. On January 19, 1999, the United States Patent and Trademark Office issued the '946 patent, entitled "Instrument for Inserting a Suppository," a copy of which is attached to this Complaint as Exhibit B. At the time of its issue, the '946 patent was assigned to Novo Nordisk A/S. NNFCAG currently is the owner of all right, title, and interest in and to the '946 patent. NNI and NNFCAG are indirect, wholly owned subsidiaries of Novo Nordisk A/S.

[1] On October 24, 2012, NNFCAG filed a reissue application which is pending as United States Application No. 13/659,605.

VAGIFEM®

10. NNI holds approved New Drug Application No. 20908 ("the Vagifem® NDA") for estradiol vaginal tablets, in a 10 mcg dosage strength, which NNI sells under the trade name Vagifem®.

11. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the '992 patent and the '946 patent are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Vagifem®.

TEVA'S ANDA

12. On information and belief, Teva has submitted ANDA No. 206388 ("Teva's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to sell, offer to sell, use, and/or engage in the commercial manufacture of generic estradiol vaginal tablets in a 10 mcg dosage strength ("Teva's Product").

13. On information and belief, Teva's ANDA refers to and relies upon the Vagifem® NDA and contains data that, according to Teva, demonstrate the bioequivalence of Teva's Product and Vagifem®.

14. By letter to NNI and NNFCAG, dated May 21, 2014, Teva stated that Teva's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '992 and '946 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva's Product (the "Paragraph IV Certification"). Teva attached a memorandum to its May 21, 2014 letter, in which it alleged factual and legal bases for its Paragraph IV Certification.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,018,992

15. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-14 of this Complaint.

16. Defendant has infringed the '992 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Teva's ANDA, by which Teva seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Teva's Product prior to the expiration of the '992 patent.

17. Defendant's sale, offer for sale, use, or commercial manufacture, of Teva's Product within the United States, or importation of Teva's Product into the United States, during the term of the '992 patent would infringe at least claims 7, 8, 9, 11, and 12 of the '992 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

18. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '992 patent.

19. Plaintiffs have no adequate remedy at law.

20. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 5,860,946

21. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

22. Defendant has infringed the '946 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Teva's ANDA, by which Teva seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Teva's Product prior to the expiration of the '946 patent.

23. Defendant's sale, offer for sale, use, or commercial manufacture, of Teva's Product within the United States, or importation of Teva's Product into the United States, during the term of the '946 patent would infringe the '946 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

24. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '946 patent.

25. Plaintiffs have no adequate remedy at law.

26. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendant and respectfully request the following relief:

A. A judgment that Defendant has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Defendant has infringed the '946 patent under 35 U.S.C. § 271(e)(2)(A);

C. A judgment that the manufacture, use, sale, or offer for sale of Teva's Product will infringe the '992 and '946 patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Teva's Product within the United States, or importing Teva's Product into the United States, prior to the expiration of the '992 and '946 patents, including any extensions;

E. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 206388, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '992 and '946 patents, including any extensions;

F. If Defendant commercially manufactures, uses, offers to sell, or sells Teva's Product within the United States, or imports Teva's Product into the United States, prior to the expiration of the '992 and '946 patents, including any extensions, a judgment awarding Plaintiffs monetary relief, together with interest;

G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other relief as the Court deems just and proper.

Dated: July 3, 2014
Newark, New Jersey

Respectfully submitted,

By: s/ David E. De Lorenzi

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